



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Maternal and Childhood Outcomes

Associated with the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Maternal and Childhood Outcomes Associated with the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

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5600 Fishers Lane

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FOR FURTHER INFORMATION CONTACT:

Jenae Benms, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Maternal and Childhood Outcomes Associated with the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Maternal and Childhood Outcomes Associated with the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)*, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/outcomes-nutrition/protocol>

This is to notify the public that the EPC Program would find the following information on *Maternal and Childhood Outcomes Associated with the Special Supplemental Nutrition Program for Women, Infants and Children (WIC)* helpful:

- A list of completed studies that your organization has sponsored for this indication.

In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.*
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

KQ 1: Among women who are eligible to participate in WIC, how is WIC participation during pregnancy associated with maternal and infant birth outcomes?

- a. Does the association vary by gestational age at WIC enrollment or duration of mother's WIC participation?
- b. Does the association vary by participant factors such as:
 - i. Age of the mother at delivery
 - ii. Race/ethnicity of mother
 - iii. Geographic location (e.g. region, urban vs. rural)
 - iv. Education of the mother
 - v. Employment status of the mother
 - vi. Marital status
 - vii. Housing (e.g. public), homelessness

KQ 2: Among infants and children eligible to participate in WIC, how is WIC participation associated with dietary and health outcomes in childhood?

- a. Does the association vary by age or duration of WIC participation?
- b. Does the association vary by participant factors such as:
 - i. Age of the mother at delivery
 - ii. Race/ethnicity of child
 - iii. Geographic location (e.g. region, urban vs. rural)
 - iv. Education of the mother
 - v. Employment status of the mother
 - vi. Marital status of the mother
 - vii. Housing (e.g. public, private), homelessness

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

PICOTS elements	KQ 1	KQ 2
Population	<p>Women who participated in WIC during pregnancy and their infants at birth up to 28 days</p> <p>Participant factors include; age of mother at delivery, race/ethnicity of mother, geographic location, education of mother, employment status of mother, marital status of mother, housing, parity, and maternal nutritional status at enrollment</p>	<p>Infants/children who participated in WIC (age from 29 days up to age 5)</p> <p>Participant factors include; age of mother at delivery, race/ethnicity of child (or mother), geographic location, education of mother, employment status of mother, marital status of mother, housing, parity of mother, and maternal and/or child nutritional status at enrollment</p>
Intervention	<p>Participation in WIC with service provisions from 2009 onwards (year and location), defined at a minimum as enrolling in WIC for one month or more</p>	<p>Participation in WIC with service provisions from 2009 onwards (year and location), defined at a minimum as enrolling in WIC for one month or more</p>
Comparison	<p>Women who were eligible for WIC, but did not participate during pregnancy, and their infants at birth up to 28 days; duration of WIC participation</p>	<p>Infants/children who were eligible for WIC, but did not participate at the age studied (ages from 29 days up to 5 years); duration of WIC participation</p>

Outcomes*	<p>Dietary practices of infants and mothers, diet quality, household food security, food purchasing</p> <p>Anthropometric status: weight status (e.g. BMI, underweight, obesity)</p> <p>Maternal: e.g. anemia, weight gain, health care utilization (prenatal, postpartum), mode of delivery, intra- and post-partum complications, morbidity and mortality</p> <p>Infant birth outcomes: e.g. gestational age, birth weight, small/large for gestational age, birth complications such as preterm delivery, hospitalization</p>	<p>Dietary practices of infants and children, diet quality, household and child food security, food purchasing</p> <p>Anthropometric status: e.g. weight-for-age, length- or height-for-age, weight-for-length, or weight-for-height percentile or Z-score, BMI-for-age percentile or Z-score, underweight, and obesity), growth velocity</p> <p>Infant and child outcomes: anemia, iron deficiency anemia, iron deficiency, primary health care utilization, immunization status, morbidity and mortality</p> <p>Child development/school performance (e.g., cognitive development, behavioral development, educational performance, school-related factors (e.g. attendance, behavior))</p>
Timing**	Studies published 2009 onwards	Studies published 2009 onwards
Setting	Any jurisdiction served by a WIC State or Local Agency	Any jurisdiction served by a WIC State or Local Agency

Study Design	Intervention trials (randomized and non-randomized), observational studies, quasi-experimental, before-after, interrupted time series	Intervention trials (randomized and non-randomized), observational studies, quasi-experimental, before-after, interrupted time series
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* Please see appendix A for the detailed list of outcomes

** Only for specific key outcomes (maternal mortality, infant mortality, child development/school performance) will studies prior to 2009 be included

Appendix A: Detailed list of outcomes by key question

Key Question 1: Among women who are eligible to participate in WIC, how is WIC participation during pregnancy associated with **maternal and infant birth outcomes**?

Outcomes		Measures
Maternal health outcomes [health risk] in: <ul style="list-style-type: none"> ➤ Pregnancy ➤ Postpartum 	Anemia Iron deficiency Iron-deficiency anemia Nutritional anemias	
	Gestational weight gain	Total gestational weight gain; IOM rec by BMI: under, within, over
	Weight status (e.g. BMI, underweight, overweight, obesity)	Pregnancy, Postpartum obesity Postpartum weight retention
	Health care utilization	Utilization of recommended prenatal care, postpartum care and other health maintenance recommendations Inter-pregnancy interval
	Morbidity	GDM Pre-eclampsia Gestational hypertension Mental Health (symptoms) Smoking, alcohol, risk behaviors
	Mode of delivery	Cesarean/Vaginal

	Intra- and post-partum complications	Prolonged labor, PROM, Postpartum hemorrhage, transfusion
	Mortality	Fetal death (stillbirth), pregnancy-related death (while pregnant or within a year of the pregnancy ending)
Dietary outcomes	Diet intake, practices and quality (infant and mother) (Diet quality measure Dietary intake (method) Diet quality score)	Breastfeeding (intention, initiation, and duration of any breastfeeding) Dietary intake (nutrient intake); diet quality measures (HEI, AHEI, DASH/Medical); glycemic load; servings of food groups, variety, adequacy and moderation components, SSB, sodium/salt, EFA); nutrient density (% fat, and by type; %CHO)
	Food purchasing behavior at the participant level	Benefit redemption, purchasing surveys
	Household food security	e.g., 18-item USDA Household Food Security Scale
Infant birth outcomes	Gestational age	Preterm, late preterm, early term, term and late term
	Birth weight	Very low birth weight Low birth weight, Normal birth weight High birth weight
	Small for gestational age Large for gestational age	

	Birth complications	preterm delivery, hospitalization, NICU stay, congenital malformations, neonatal (live birth and death within 28 days) or infant (within first year of life after live birth) death
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BMI=Body mass index; GDM=Gestational diabetes mellitus; PIH=pregnancy-induced hypertension; PROM =Prelabor rupture of the membranes; USDA =United States Department of Agriculture; AHEI=Alternative Healthy Eating Index; DASH =Dietary Approaches to Stop Hypertension; HEI =Healthy Eating Index; SSB =sugar-sweetened beverage; EFA=Essential Fatty Acids; CHO= Carbohydrates; NICU= Neonatal Intensive Care Unit; WIC = Special Supplemental Nutrition Program for Women, Infants and Children

Key Question 2: Among *infants and children eligible* to participate in WIC, how is WIC participation associated with dietary and health outcomes in childhood (to age 17 years)?

Outcomes		Measures
Health outcomes	Anemia Iron deficiency anemia, nutritional anemias, iron deficiency	
	Child growth, anthropometric status	weight-for-age, length- or height-for-age, weight-for-length, or weight-for-height percentile or Z-score, BMI-for-age percentile or Z-score, underweight, overweight, obese; growth velocity (change in size/status or z-score over time)
	Healthcare Utilization	Well child visits Immunization status

	Morbidity	<p>otitis media, allergies, gastrointestinal respiratory infections, asthma, immunization status,</p> <p>Pre-diabetes, Diabetes mellitus, elevated blood pressure/hypertension, hyperlipidemia</p>
	Mortality	<p>Infant mortality</p> <p>Child mortality</p>
Dietary outcomes	Dietary practices of infants and children	<p>Infants: maternal intention to breastfeed; Ever breastfed or any breastfeeding; Exclusive breastfeeding (initiation and duration); Duration of any breastfeeding; introduction of formula (timing); timing of solids introduction (< 4 months, < 6 months); cereal in the bottle; timing of cow's milk introduction (< 12 months); food group servings; nutrient intakes</p> <p>Children (1-2):</p> <p>food group servings, groups for variety, adequacy and moderation; added sugars, SSB, type of milk; fruit juice; dietary diversity; nutrient intakes, nutrient density measures (iron, zinc, calcium, %fat (total and by type)) energy density</p>
	Diet quality	<p>Children 2-5: [HEI, AHEI, food group servings (adequacy and moderation, added sugars, SSB), type of milk; fruit juice]</p> <p>Nutrient intakes and nutrient density measures (iron, zinc, calcium, %fat (total and by type)) energy density</p>

	Food purchasing behavior at the participant level	Benefit redemption, purchasing surveys
	Household and child food security	18-item USDA Household Food Security Scale
Child development/school performance	Academic development	Pre-school or Head Start (e.g., attendance, behavior) K-12 educational performance, school-related factors (e.g. attendance, behavior) ADHD, conduct disorders, mental health
	Child development (behavioral development, cognitive development; cognitive performance)	BSID II/III; WPPSI, WISC, other standardized measures or specific constructs

ADHD =Attention deficit hyperactivity disorder; AHEI=Alternative Healthy Eating Index; HEI =Healthy Eating Index; SSB =sugar-sweetened beverage; WISC=Wechsler Intelligence Scale for Children; BSID =Bayley Scales of Infant Development; WPPSI = Wechsler Preschooland Primary Scale of Intelligence

Dated: December 10, 2020.

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Associate Director.

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